

Combating the Opioid Abuse Epidemic: A Shared Responsibility that Requires Innovative Solutions

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Every day, the opioid abuse epidemic affects communities across America. This white paper presents McKesson's recommendations to improve prescribing and dispensing practices towards our country's shared goal: to eliminate the detrimental impact of the opioid abuse epidemic. Our recommendations include the following:

- Require all payers and providers to use opioid management programs
- Require e-prescribing for all controlled substances
- Harness the Food and Drug Administration's Risk Evaluation and Mitigation Strategies Program
- Fully leverage data analytics to identify patients most at risk and integrate a National Patient Safety Network into the pharmacy dispensing process
- Improve information sharing among Prescription Drug Monitoring Programs
- Permit partial refills to reduce risks associated with an excess of unused pills

The white paper also highlights McKesson's efforts to promote a secure supply chain and educate and equip our customers, physicians and pharmacists. As healthcare reform and other issues capture headlines, we must continue to do all we can, together, to combat this public health challenge.

The Crisis

Our country is in the midst of a serious opioid abuse epidemic, which is affecting every community in America. It has claimed victims from all races, ages, and socio-economic groups. According to the Centers for Disease Control & Prevention (CDC), from 2000 to 2014, nearly half a million Americans died from drug overdoses.¹ In 2015, more than 15,000 people died from overdoses involving prescription opioids.² Additionally, each day over 1,000 people are treated in emergency departments for not using prescription opioids as directed.³ The National Institute on Drug Abuse (NIDA) has cited the increased volume of opioid prescriptions as a driving factor for the severity of the current crisis.⁴

The opioid epidemic is a multi-faceted problem that cannot be solved by focusing on individual parts of the healthcare system. It must be addressed through a comprehensive approach that includes the doctors who write the prescriptions, the pharmacists who fill them, the distributors who fill and deliver pharmacies' orders, the manufacturers who make and promote the products, and the regulators who license the above activities and determine supply.

McKesson is fully committed to working with all stakeholders to protect the supply chain and help prevent diversion while ensuring appropriate treatments are available to patients. With a 360-degree view of healthcare and customers across industry and government, McKesson is uniquely positioned to advocate for a comprehensive set of policy and business solutions that will harness the power of technology to promote improved prescribing and dispensing. The implementation of these policy and business solutions could significantly slow the abuse and diversion of opioids, to the benefit of patients and their families.

Current Initiatives and Proposals

Policymakers, manufacturers, insurers, and other stakeholders have launched numerous initiatives and proposed a wide range of policies aimed at curbing misuse of opioids, including pill disposal requirements, product stewardship, enhanced provider and pharmacist education, Medicare beneficiary "lock in," and various pill limitation measures.

In January 2016, the **Centers for Medicare & Medicaid Services (CMS)** released its opioid management strategy, which outlines the agency's plan to address the national opioid epidemic. The strategy features four key policy areas⁵: (1) implementing more effective person-centered and population-based strategies to reduce the risk of opioid use disorders, overdoses, inappropriate prescribing, and drug diversion; (2) expanding naloxone (an overdose reversal drug) use, distribution, and access, when clinically appropriate; (3) expanding screening, diagnosis, and treatment of opioid use disorders, with an emphasis on increasing access to medication-assisted treatment; and (4) increasing the use of evidence-based practices for acute and chronic pain management.

The Department of Veterans Affairs (VA) has engaged in a comprehensive approach aimed at reducing the use of opioids among veterans using VA healthcare.⁶ The VA's Opioid Safety Initiative (OSI) is an effort to improve the quality of life for veterans suffering from chronic pain. The program features patient management initiatives including Pain Coach, which is a pain management application available for download by patients receiving pain management treatments, a Veterans' Health Library, a Patient/Family Management Toolkit, and resources for Pain Management on My HealthVet. All of these applications allowed veterans to better manage their pain without the use of opioids.⁷ The VA has also been on the leading edge of PDMP interoperability, naloxone distribution, drug take back and opioid management programs.

In July 2016, **Congress** passed the Comprehensive Addiction and Recovery Act of 2016 (CARA) with overwhelming bipartisan support. CARA focuses primarily on treatment, recovery, law enforcement, criminal justice reform, and access to overdose reversal drugs.

Also in July 2016, the **National Governors Association (NGA)**, released a resource for state governments to address the opioid epidemic, titled *Finding Solutions to the Prescription Opioid and Heroin Crisis: A Road Map for States*.⁸ *A Road Map for States* is a thoughtful and comprehensive set of evidence-based public policy recommendations and public health strategies focused on prevention and response to opioid misuse and overdose.

These are all thoughtful steps in taking meaningful action to combat the scourge of opioid abuse and diversion; and yet, there is more work to be done.

McKesson's Public Policy Recommendations

Patients taking prescription opioids interact with the healthcare system at least twice in order to access their medications. The first interaction takes place when the prescriber writes a prescription, and the second interaction takes place at the pharmacy when the prescription is dispensed to the patient. There are significant opportunities to engage at both encounter points to ensure that opioids are being prescribed and dispensed in an appropriate manner.

The proposals outlined below are aimed at establishing mechanisms to improve clinical treatment decisions by providing better information at the point of prescribing. Also included are a complementary set of policies that would similarly deliver actionable information to dispensing pharmacists.

Section 1: Improve Prescribing Practices for Opioids

In some instances, patients can obtain inappropriate access to prescription opioid medication by manipulating the prescription process. For example, some patients are able to interact with multiple doctors or pharmacies to acquire opioids that may not be clinically necessary. Multiple strategies can be deployed to improve opioid prescribing practices. Implementing e-prescribing requirements can limit opportunities for individuals to forge paper prescriptions for opioids. Providing comprehensive, accurate, and up-to-date information about a patient's prescription utilization history would significantly improve a physician's ability to identify instances where prescribing an opioid may be inappropriate. Additionally, improving and enhancing provider education about when and how to prescribe opioids, as well as recognizing any potential abuse, and the ability to carefully review a patient's prescription history – all would enhance the safety of prescribing practices.

Recommendation 1: Require all payers and providers to use opioid management programs

Many public and private health plans, pharmacy benefit managers (PBMs), and hospital and physician organizations have adopted opioid management programs to curb overprescribing, misuse, and abuse. These programs often combine multiple strategies to improve decision-making when prescribing opioids and incorporate evidence-based clinical guidelines. A number of payers have adopted the CDC clinical guidelines for prescribing opioids, released in March of 2016. By the end of 2017, 21 states will use these guidelines for Medicaid fee-for-service and 11 states will require that Medicaid managed care organizations adopt them.⁹ McKesson supports broader awareness and adoption of the CDC and other evidence-based clinical practice guidelines. We believe embedding these guidelines at the point of care (e.g., integration into e-prescribing, electronic health records, or other care management processes) can improve prescribing practices both in workflow and at the right time along the care continuum.

Several opioid management programs have had promising results. The emerging model implemented by Blue Cross Blue Shield of Massachusetts (BCBS-MA) is reporting successful outcomes and can serve as a model for other stakeholders to consider. Over a three-year period, the BCBS-MA program reduced the risk of substance use disorders and other health issues related to long-term use of opioids. The program eliminated an estimated 21.5 million doses of opioid-based medications in the communities served by its plans and reduced claims for long-acting opioids by approximately 50 percent by switching patients to short-acting pain treatments.¹⁰

Key elements of the program include, but are not limited to: (1) a comprehensive treatment plan between doctor and patient that outlines the expectations of both parties and considers non-narcotic treatment options; (2) a clinical risk evaluation for addiction that is signed by the patient; (3) choosing a single pharmacy or pharmacy chain to be used for all opioid prescriptions; (4) a prior authorization requirement for all new short-acting opioid prescriptions for more than 30 days and for all new long-acting opioid prescriptions; and (5) a three-day supply of short-acting opioids if prior authorization isn't immediately available, allowing time for authorization.

The BCBS-MA program features effective patient safety measures while ensuring access to care for patients in need. Cancer patients and terminally-ill patients are exempt from many of the authorization requirements, which is important for every opioid management program to contemplate since it is estimated that pain occurs in up to 70 percent of patients with advanced cancer.¹¹ Requiring a broader adoption of the key elements of BCBS-MA's opioid management programs could have a significant impact on the national opioid epidemic.

Recommendation 2: Require e-prescribing for all controlled substances

Traditional handwritten prescriptions can be forged, altered, or diverted and can enable illegal access to prescription opioids.¹² Electronic prescribing (e-prescribing) allows prescriptions to be transmitted to pharmacies

securely without risk of alteration or diversion, and prescribers can be authenticated before dispensing of controlled substances and prescriptions. The American Journal of Pharmacy Benefits (AJPB) has recommended e-prescribing to help address the misuse and diversion of opioid medications.¹³ E-prescribing of controlled substances (EPCS) is currently permitted in all 50 states, yet is only required in New York, Maine, and Minnesota. There is significant variability across the states in terms of e-prescribing capabilities and behaviors, and not all pharmacies or physicians' offices are capable of transmitting prescriptions electronically.¹⁴ For example, in 2015, 82% of pharmacies in Nebraska were EPCS-enabled, along with 15% of prescribers.¹⁵ By contrast, for the same year in Florida, 74% of pharmacies were EPCS enabled along with only 2% of prescribers.¹⁶ Nationally, just 8% of physicians serve in practices that allow for the use of this technology to prescribe controlled substances like opioids.¹⁷ Research on EPCS has been scarce, but surveys have shown that prescribers are generally optimistic about the benefits of EPCS.¹⁸ A nationwide e-prescribing requirement for opioids could be a promising solution for reducing forged prescriptions and strengthening the efficacy of state prescription drug monitoring programs (PDMPs) across the country.

Recommendation 3: Harness FDA's Risk Evaluation and Mitigation Strategies (REMS) Program

The Food and Drug Administration (FDA) recognizes that there are risks associated with the use of certain drugs or classes of drugs. In order to manage these risks, the FDA requires drug manufacturers to create risk evaluation and mitigation strategy programs, or REMS, which include activities such as creating a medication guide and communication plan for healthcare professionals and distributors. These initiatives can help identify potential risks, harmful drug interactions, and other guidelines for safe use and proper disposal of opioids. Given the potential safety risks associated with opioids, the FDA has a class-wide REMS policy for all extended release and long acting (ER/LA) opioids. However, not all long-acting opioids have been subject to REMS requirements. The FDA recently announced that it intends to require a REMS for all forms of opioids to "ensure the benefits of these drugs continue to outweigh the risks of misuse, abuse, addiction, overdose and death."¹⁹ McKesson supports the FDA's initiative.

The impact of opioid REMS has been hindered by low awareness of, and limited participation in, the physician education programs offered by drug manufacturers. For example, the voluntary REMS for ER/LA opioids fell short of its targeted prescriber goal. In the first two years, 37,512 prescribers completed the training, accounting for just under half (47 percent) of the targeted 80,000 prescribers.²⁰ A recent PriMed study involving 441 healthcare providers that received REMS training and 4,669 providers that were not trained, found that those who had REMS training had a 10% drop in ER/LA prescribing compared with a 4% increase in the untrained population.²¹

To improve effectiveness of the opioid REMS program, McKesson recommends: (1) implementing REMS requirements for all long-acting opioids as soon as possible; (2) increasing provider participation in REMS educational activities; and (3) improving the educational programs associated with REMS requirements and beyond. An exemption should be granted for cases in which a physician cares for a patient with a terminal condition, since certain REMS requirements (e.g., requiring physicians to document that terminally-ill patients understand the risk of addiction and abuse) could contribute to the patient avoiding the medication due to fear of addiction.

Section 2: Improve Dispensing Practices for Opioids

Dispensing pharmacists are a strong second line of defense to detect potential opioid abuse or misuse. Unlike prescribers who often do not engage with patients during refills, pharmacists handle refill prescriptions and the interaction with patients. Therefore, they must be a part of the solution. To maximize a dispenser's ability to identify potential instances of fraud or opioid misuse, it is vital that pharmacists and their staff have easy access to reliable, up-to-date information about a patient's prescription history. Further, to minimize the risk of opioid misuse, patients must not be prescribed more medication than they will need to manage their medical conditions.

Recommendation 4: Integrate a National Patient Safety Network into the pharmacy dispensing process

Under the current system, which the National Council for Prescription Drug Programs (NCPDP) describes as "systematically burdensome," pharmacists must leave their workstations to check a PDMP.²² Unsurprisingly, research indicates that pharmacists do not always consult PDMPs. For example, a survey of pharmacists in Maine found that, in 2014, only 56 percent were using the state's PDMP.²³ Delivering alerts through the very same system that pharmacists use as part of their dispensing process would save significant time and, most importantly, would increase the likelihood that pharmacists consult their PDMPs.

To make the most informed dispensing decisions, pharmacists need access to robust, real-time information that can access and analyze data across all 50 states. One tool that can be used to increase patient safety is an automated,

clinically-based system that notifies dispensers in real-time and in workflow when a drug may present a safety issue to a patient (e.g., non-medical use, miscalculated dosage, or drug interactions).

This tool, a National Patient Safety Network (“Network”), as envisioned by NCPDP would identify “red flags” and alert dispensers whenever patient safety issues are identified. For example, in instances where there may be non-medical use of opioids, the Network would notify the pharmacist who could *voluntarily* check the PDMP before dispensing. The Network would complement PDMPs in two significant ways by: (1) providing alerts to dispensing pharmacists that are based on real-time, comprehensive prescription history data for patients, regardless of setting of care, and (2) promoting more effective use of PDMP information since pharmacists would know when to consult the PDMP rather than having to check it for all patients.

The Network could also benefit physicians, who according to a 2014 survey cited the time-consuming nature of retrieving data from PDMPs as a barrier to their use.²⁴ The same survey found that while doctors prescribed opioids for an average of 35 patients a month, they retrieved data from a PDMP for an average of only eight patients a month.²⁵ The NCPDP solution proposes that all electronic prescriptions, as well as all pharmacy dispensing activity, are evaluated against the Network.

Recommendation 5: Improve information sharing among PDMPs

PDMPs are an important tool for pharmacists who serve as a crucial line of defense in identifying and avoiding potential opioid misuse and abuse. However, the data in PDMPs are typically limited to the prescription data from within the state the pharmacist is operating in. This means that a pharmacist searching a PDMP in one state may not have access to data from another state’s PDMP. The data collected by PDMPs vary by state²⁶ and, according to a December 2016 report by Pew Charitable Trusts, data sharing between PDMPs is often slow.²⁷ Establishing a mechanism to exchange opioid prescription data across all state PDMPs would enable standardized data to be shared on a real-time basis. For example, a system like the one envisioned by CommonWell® Health Alliance, a vendor-neutral platform that breaks down barriers that currently inhibit effective, interoperable exchange of health data, would enable prescribers and dispensers to access comprehensive data from PDMPs from across the country that captures all opioid prescription activity, regardless of setting of care. The Network described above can provide PDMPs more robust real-time data, if states elect for that data to be incorporated into their PDMPs.

Recommendation 6: Permit partial refills to reduce risks associated with an excess of unused pills

Prior to 2016, as Schedule II products, opioid prescriptions were not permitted to be refilled. This may have led some prescribers who anticipate an increased need for pain management in patients with acute pain to prescribe a greater supply of medication than necessary. This practice has resulted in an excess of unused pills. According to a study by the Johns Hopkins Bloomberg School of Public Health, six out of 10 adults prescribed opioid painkillers have leftover pills.²⁸ Allowing patients to partially refill their prescriptions increases the chances that a patient will be prescribed the exact number of pills that he or she needs, thereby reducing the risk of these “extra” pills being improperly disposed, lost, stolen, sold or given to others.

States and federal lawmakers have begun to take action aimed at limiting the risks associated with excess pills. For example, New Jersey recently enacted a law that imposed a five-day limit on a patient’s first opioid prescription.²⁹ At the federal level, CARA permits a prescription for a Schedule II controlled substance to be partially filled if: (1) it is not prohibited by state law; (2) the partial fill is requested by the patient or the practitioner who wrote the prescription; and (3) the total quantity dispensed in all partial fillings does not exceed the total quantity prescribed.³⁰ Providing flexibility to allow patients and prescribers to reduce the number of unused opioid pills limits opportunities for diversion or misuse of these medications. A swift and comprehensive implementation of this policy, along with proper coordination with the states, can reduce the volume of unused pills and the risk of diversion and misuse.

Section 3: Our Efforts

McKesson understands that thoughtful and innovative public policy solutions alone are not enough. We are committed to working closely with our partners and customers to fight the opioid abuse epidemic.

Promoting a Secure Supply Chain

McKesson plays an important role in the proper disposal of medication. We are committed to ensuring unused medications are properly collected from our customers and our distribution centers and safely processed out of the supply chain. Over the last three years, we have worked with reverse distributors to appropriately dispose of, and in many instances, recycle, an average of 7.2 million products a year. In addition, we leverage our unique relationship with our customers to educate pharmacists about medication disposal so they in turn can educate their patients.

McKesson provides its Health Mart® pharmacists with “Drug Take Back Solutions” information, which demonstrate how they can partner with local law enforcement in getting unwanted or expired medications off the street.

McKesson operates a robust Controlled Substances Monitoring Program (CSMP) to help us identify and report suspicious orders. We also are utilizing advanced analytical tools to closely monitor our customers’ purchases. We are committed to continuing to make enhancements as needed to ensure our CSMP remains an effective contribution in our country’s battle with opioid diversion and abuse.

Educating Our Customers

An FDA advisory panel has endorsed mandatory training for doctors who prescribe opioids as part of the efforts to stem the national epidemic of deaths and addiction related to these drugs. McKesson supports improvements in both formal medical education and continuing medical education to better inform clinical practice in pain management. MedTrainer, a compliance and regulatory training tool offered to McKesson’s provider customers, provides training opportunities focused on responsible opioid prescribing and on recognition of drug seeking behavior and substance abuse disorders.³¹

Similarly, McKesson provides its nearly 5,000 HealthMart® independent community pharmacies with relevant information, tools, and resources about prevention of opioid abuse. As independent business owners, Health Mart® members are empowered to become advocates for drug abuse prevention in their communities, starting with their own pharmacies. All HealthMart® pharmacies are equipped with the *Health Mart Operations Toolkit*, an online portal where pharmacists can access resources created specifically to help prevent drug abuse in their communities, including: (1) education and training courses available for the entire pharmacy’s staff; (2) drug abuse prevention solutions, which contains news, drug take back solutions, education, and outreach ideas; (3) best practices and practical advice for pharmacists and technicians to prevent drug abuse when filling prescriptions; and (4) community outreach resources with strategies to promote drug abuse prevention at the local level.

Conclusion

Absent thoughtful and innovative solutions, the disturbing impact of opioid abuse and misuse will continue unabated. Meaningful solutions require the partnership of a variety of stakeholders, including doctors, pharmacists, distributors, manufacturers, payers, policymakers, and regulators. We believe the innovative solutions presented above offer a practical and unique approach to both the improvement of prescribing and dispensing practices and processes.

As a company, we are committed to advancing impactful solutions and continuing to innovate in our own processes. We stand ready to collaborate with lawmakers and all stakeholders and partners in the pharmaceutical supply chain to address our nation’s devastating opioid abuse epidemic. For more information or to partner with McKesson Public Affairs on these policy solutions, contact PublicAffairs@McKesson.com.

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